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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 12/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/856,415	TALTON ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-44 and 48-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-44 and 48-70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Amendment (complete claim listing) filed 07/08/04 and Applicant's Arguments/Remarks filed 05/28/04 is acknowledged.

Claims 28-44 and 48-70 are pending. Claims 28, 29, 31 and 66-68 have been amended. Claims 28-44 and 48-70 remain rejected.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 68-70 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-36 of U.S. Patent No. 6,406745 B1 (Talton) in view of Lowndes *et al.* (US Pat. No. 5,499,599). Although the conflicting claims are not identical, they are not patentably distinct from each other because similar subject matter has

been claimed. Instant claim 68 is drawn to a method of preparing a medicament, by providing a plurality of core drug particles, having an average particle size of less than 500 μm in diameter, and depositing onto the surface of plurality of core drug particles, at least a first coating layer that comprises a plurality of polymeric coating particles, said coating layer being biodegradable, biocompatible, wherein the average thickness of the coating layer is between 1 and 500 nm, said depositing step by a process comprising pulsed laser ablation under vacuum, wherein said vacuum is between 1 mTorr and 1 Torr. U.S. Pat. *6,406,745 B1* is also drawn to a method of coating a particulate core material. The only significant distinction observed between instant claims 68-70 and Pat. '745 is that '745 recites a pressure of 'about 10 Torr or higher' whereas instant amended claim 68 recites 'between 1 mTorr and 1 Torr.' The secondary reference of Lowndes *et al.* U.S. Pat. '599 is relied upon for its teaching of a 'method for continuous control of composition and doping of pulsed laser deposition films by pressure control' whereby Lowndes *et al.* teach that the 'Thickness of each layer is controlled by the number of laser shots' (col. 5, lines 27-33) and also teach that 'by controlling the pressure of the gas within the chamber, the composition of the deposit grown upon the substrate can be accurately and continually controlled. Furthermore, by altering gas pressure during the film growth process, the composition of adjacent layers of the film being formed are altered accordingly' (see col. 3, lines 7-12). Therefore, since Patent '599 demonstrates the co-relationship between varying pressure and varying coating thickness, it is deemed obvious to one of ordinary skill in the art to adjust the pressure or Torr in order to obtain the desired or intended coating thickness. Hence, claims 68-70 remain rejected under Non-statutory Obviousness-Type Double Patenting.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 28, 30-44, 48, 50-54 and 59-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moro *et al.* (U.S. Pat. No. 5,223,244) in view of Green *et al.* (US Pat. No. 5,976,577).

Moro *et al.* teach aerosol compositions comprising at least one propellant, a solvent and a composite powder, whereby a sheath powder, having a particle size of 1/5 or less of a core powder is attached to the core powder that has an average particle size of 0.1 to 100 μm to form a composite powder (see reference column 2, lines 12-44); (col. 4, lines 26-37). The amount of the composite powder is preferably 0.1% to 30% by weight in the total amount of the aerosol composition (col. 5, lines 46-53). In Example 10, at column 14, lines 6-24, Moro et al. demonstrate the teaching of a powder spray, which comprises an aerosol spray that contains an active ingredient potassium glycyrrhizinate. The composite powder is granular tetrafluoroethylene (1 μm) with a kaolin coating thickness of 0.1 μm. After components (1) to (5) were mixed, the mixture was filled in an aerosol can, followed by filling components (6) and (7) to obtain a powder spray. The spray was found to have a good powder dispersibility and usability.

According to Moro et al., as the core powder of the composite powder usable, is any desired organic powder with a density of 0.7 to 2.0 and an average particle size of 0.1 to 100 μm

can be used, and the powder used for the core can be in the form of a spheroid, plate, granule or needle (col. 2, lines 12-19). Moro et al. teach at column 4, lines 35-37, teach that the core powder is substantially completely covered by the coating powder and with a superior stability against separation. As the method of preparing the composite powder, the composite powder can be prepared by mixing the core powder and the sheath powder by the dry process or the wet process (col. 3, lines 33-37).

Moro et al. are deficient in the sense that they do not explicitly teach that the coating layer is a continuous and non-porous layer. It is the Examiner's position that there is no criticality observed in the use of Applicant's continuous or non-porous layer since the instant specification permits the use of both a continuous and discontinuous coating layer (see specification pgs. 2 and 5, lines 29-32). Furthermore, it is deemed obvious to one of ordinary skill in the art to employ a continuous and non-porous coating layer to obtain a sustained or controlled rate of delivery of the active ingredient. Such skill is also evident from the reference of Green *et al.* (see below).

Green *et al.* teach a process for preparing rapidly disintegrating solid dosage forms containing drug particles, wherein the drug particles may be *coated or uncoated* with a water-insoluble polymer or lipid material, resulting in a dosage form that exhibits delayed release of the drug for a sufficient period of time to provide for controlled or *sustained release* of the drug after swallowing. The drug particles have a size such that the coatings can be formed thereon which are sufficiently *intact and continuous* to prevent or minimize loss of drug during processing. The coarse drug particles have an average particle size up to about 500 μm. In this size range, it is

possible to apply a *uniform intact coating* on the particle in order to achieve efficient freeze-dried dosage forms with slow drug release rate (see reference cols. 1, line 5 – col. 3, line 22); (col. 5, lines 1-47).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the combined teachings of Moro *et al.* and Green *et al.* because Moro *et al.* teach an active ingredient formulation (i.e., glycyrrhizinate) whereby a core powder is coated and covered by a sheath powder and similarly Green *et al.* teach a dosage form comprising drug particles that are either coated or uncoated and if coated, provide a continuous intact coating on the drug particles in order to provide a sustained release of the active ingredient. The expected result would be a continuously coated, non-porous pharmaceutical formulation that exhibits a sustained release of the active drug material, as similarly desired by the Applicant(s).

Claims 28, 30-44 and 48-61 and 66-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakon *et al.* (US Pat. No. 5,972,388) in view of Green *et al.* (US Pat. No. 5,976,577).

Sakon *et al.* teach an ultrafine particle powder for inhalation and method for the production whereby the particle powder is produced by spray-drying a mixture of active agent and a lower alkyl ether cellulose wherein the active ingredient and cellulose are either dissolved or suspended in a solution and then spray-dried into particles, whereby 80% of the particles have a particle size in the range of 0.5 to 10 μm. Particles smaller than this size do not appear to be critical since size criticality appears to depend upon administration to lower airways, which is

achieved with the teachings of Sakon. Such is also the case for thickness of the coating layer. According to Sakon et al., it is desirable that the medicament is not readily removed by cilia and retained at the site to be deposited. Sustained release of the medicament while it is retained further enhances its efficacy (col. 2, lines 35-40). Sakon et al. teach that the active ingredient includes steroids, such as triamcinolone acetonide and flunisolide, antiallergics, chemotherapy medicaments, antitussives and bronchodilators. These medicaments may be used singly, or as a mixture of two or more thereof unless the mixture is incompatible (col. 9, lines 10-26).

Sakon *et al.* do not teach that the coating layer is a continuous and non-porous layer. It is the Examiner's position that there is no criticality observed in the use of Applicant's continuous or non-porous layer since the instant specification permits the use of both a continuous and discontinuous coating layer (see specification pgs. 2 and 5, lines 29-32). Furthermore, it is deemed obvious to one of ordinary skill in the art to employ a continuous and non-porous coating layer to obtain a sustained or controlled rate of delivery of the active ingredient. Such skill is also evident from the reference of Green *et al.* (see below).

Green *et al.* teach a process for preparing rapidly disintegrating solid dosage forms containing drug particles, wherein the drug particles may be *coated or uncoated* with a water-insoluble polymer or lipid material, resulting in a dosage form that exhibits delayed release of the drug for a sufficient period of time to provide for controlled or *sustained release* of the drug after swallowing. The drug particles have a size such that the coatings can be formed thereon which are sufficiently *intact and continuous* to prevent or minimize loss of drug during processing. The coarse drug particles have an average particle size up to about 500 μm. In this size range, it is

possible to apply a *uniform intact coating* on the particle in order to achieve efficient freeze-dried dosage forms with slow drug release rate (see reference cols. 1, line 5 – col. 3, line 22); (col. 5, lines 1-47).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the combined teachings of Sakon *et al.* and Green *et al.* because Sakon *et al.* teach an ultrafine particle powder formulation comprising medicaments (i.e., triamcinolone acetonide) whereby the particle powder is produced by spray-drying a mixture of active agent and a lower alkyl ether cellulose to provide a sustained release of the medicament and similarly Green *et al.* teach a dosage form comprising drug particles that are either coated or uncoated and if coated, provide a continuous intact coating on the drug particles in order to provide a sustained release of the active ingredient. The expected result would be a continuously coated, non-porous pharmaceutical formulation that exhibits a sustained release of the active drug material, as similarly desired by the Applicant(s).

Claims 28, 30-44, 48, 59-61 and 66-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanes *et al.* (US Pat. No. 5,855,913) in view of Green *et al.* (US Pat. No. 5,976,577).

Hanes et al. teach biodegradable aerodynamically light particles incorporating a surfactant on the surface for pulmonary drug delivery whereby the particles are produced by emulsifying active agent in a polymer, such as poly(lactic acid) or PLA; or poly(glycolic acid) or PGA, in a volatile solvent. After mixing, the mixture is spray-dried and the volatile solvent is evaporated to leave the drug particle enclosed within the polymer. The particles are taught to be

as small as 2 μm and can also have a mean diameter of between 5 μm and 30 μm. Particles smaller than 2 μm do not appear to be critical since size criticality appears to depend upon administration to lower airways, which is achieved with Hanes et al. Such is also the case for the thickness of the coating layer (see reference col. 5, line 16 – col. 8, line 56) and Abstract. Hanes et al. teach that the aerodynamically light particles are highly suitable for inhalation therapies, particularly in controlled release applications (col. 8, lines 54-56). Various therapeutic agents may be employed in the formulation, including antibiotics and anti-asthmatic agents (col. 10, lines 3-49).

Hanes et al. do not explicitly teach that the coating layer is a continuous and non-porous layer. It is the Examiner's position that there is no criticality observed in the use of Applicant's continuous or non-porous layer since the instant specification permits the use of both a continuous and discontinuous coating layer (see specification pgs. 2 and 5, lines 29-32). Furthermore, it is deemed obvious to one of ordinary skill in the art to employ a continuous and non-porous coating layer to obtain a sustained or controlled rate of delivery of the active ingredient. Such skill is also evident from the reference of Green *et al.* (see below).

Green *et al.* teach a process for preparing rapidly disintegrating solid dosage forms containing drug particles, wherein the drug particles may be *coated or uncoated* with a water-insoluble polymer or lipid material, resulting in a dosage form that exhibits delayed release of the drug for a sufficient period of time to provide for controlled or *sustained release* of the drug after swallowing. The drug particles have a size such that the coatings can be formed thereon which are sufficiently *intact and continuous* to prevent or minimize loss of drug during processing. The

coarse drug particles have an average particle size up to about 500 μm. In this size range, it is possible to apply a *uniform intact coating* on the particle in order to achieve efficient freeze-dried dosage forms with slow drug release rate (see reference cols. 1, line 5 – col. 3, line 22); (col. 5, lines 1-47).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the combined teachings of Hanes *et al.* and Green *et al.* because Hanes *et al.* teach aerodynamically light drug particles contained within biodegradable polymers that provide for controlled release of the active ingredient for use in pulmonary drug delivery and similarly Green *et al.* teach a dosage form comprising drug particles that are either coated or uncoated and if coated, provide a continuous intact coating on the drug particles in order to provide a sustained release of the active ingredient. The expected result would be a continuously coated, non-porous pharmaceutical formulation that exhibits a sustained release of the active drug material, as similarly desired by the Applicant(s).

Claims 62-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moro *et al.* (US Pat. No. 5,223,244) or Sakon *et al.* (US Pat. No. 5,972,388) or Hanes *et al.* (US Pat. No. 5,855,913) in view of Bucks *et al.* (US Pat. No. 6,277,364).

The teachings of Moro *et al.* ('244), Sakon *et al.* ('388) and Hanes *et al.* ('913) have been discussed above. Moro *et al.*, Sakon *et al.* and Hanes *et al.* do not teach the inclusion of a kit having instructions.

Bucks *et al.* ('364) teach aerosol formulations that include kits and packages that comprise labeling instructions for application of the composition for the protection of skin. The

labeling instructions include directions on the amount and frequency of application, methods of removal, suggested storage conditions, shelf life expectancy, precautions or contraindications, and so forth (see reference column 5, line 65 – col. 6, line 7); (claim 4).

Therefore, it would have been obvious for one of ordinary skill in the art at the time the invention was made to use the combined teachings of either Moro et al., Sakon *et al.* or Hanes *et al.* with Bucks *et al.* because Moro et al., Sakon et al. and Hanes et al. all teach powder formulations in aerosol formulations and similarly Bucks *et al.* teach aerosol formulations that also include kits and packages comprising specific instructions (i.e., method of use, storage conditions, shelf-life extent) for the medicament. The expected result would be effective kit or packaged aerosol formulations that provide for ease and safety of usability.

Claims 29 and 68-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moro *et al.* (US Pat. No. 5,223,244) or Sakon *et al.* (US Pat. No. 5,972,388) or Hanes *et al.* (US Pat. No. 5,855,913) in view of Lowndes et al. (US Pat. No. 5,499,599) and further in view of Green et al. (US Pat. No. 5,976,577).

The teachings of Moro *et al.* ('244), Sakon *et al.* ('388) and Hanes *et al.* ('913) are delineated above.

They are lacking in that they do not teach a process of *pulsed laser ablation* and do not explicitly teach a continuous, non-porous coating layer.

Lowndes *et al.* teach a method for continuous control of composition and doping of *pulsed laser deposited films* by pressure control, wherein by controlling the pressure of the gas

within the chamber, the composition of the deposit grown upon the substrate can be accurately and continually controlled. According to Lowndes *et al.*, the thickness of each layer was controlled by the number of laser shots. By varying the gas pressure between two limiting values, and maintaining each pressure for a fixed number of laser shots, structures with highly reproducible layer thickness and composition were fabricated (see column 4, lines 7-18); (col. 5, lines 27-34). Lowndes *et al.* teach in Fig. 1 at column 2, line 59 – col. 3, line 5, that an ultra-low pressure of about *10 Torr or less* was obtained.

Therefore, it would have been obvious to one of ordinary skill in this art at the time of the invention to use the teachings of Lowndes *et al.* within Moro *et al.,* Sakon *et al.* or Hanes *et al.* because Lowndes *et al.* explicitly teach that films and layers with varied coating thickness are produced by controlling by the number of laser shots and varying gas pressure using the pulsed laser ablation method and vividly teaches the co-relationship between adjusting pressures and coating thickness and similarly Moro *et al.*, Sakon *et al.* and Hanes *et al.* teach formulations comprising an array of coating layers and thicknesses. The expected result would be effective thin film materials obtained by pulsed laser techniques, as similarly desired by the Applicant(s).

As stated previously, Moro *et al.* ('244), Sakon *et a*l. ('388) and Hanes *et al.* ('913) do not explicitly teach a continuous, non-porous coating layer.

Green *et al.* ('577) is relied upon for its teaching of drug particles that may be *coated or uncoated* with a water-insoluble polymer or lipid material, resulting in a dosage form that exhibits delayed release of the drug for a sufficient period of time to provide for controlled or

sustained release of the drug after swallowing. The drug particles have a size such that the coatings are sufficiently *intact and continuous* to prevent or minimize loss of drug during processing.

Hence, it would have been obvious to one skilled in the art at the time the invention was made to incorporate continuous, non-porous coatings on drug particles if sustained release properties were desired, or discontinous, porous coatings if rapid release was intended. The expected result would be a particulate/active ingredient formulation with either sustained or immediate release rate properties.

Response to Arguments

Applicant's arguments filed 05/28/04 have been fully considered but they are not persuasive.

Firstly, Applicant argued, "Applicant's process of laser ablation permits formation of continuous nanoscale coatings on 50 μm (or less) core particles. Such coated particles are not disclosed by any of the references cited herein". Applicant also argued regarding the attached paper (Maa *et al.*) and US Pat. No. 5, 437,889 (Jones et al) to demonstrate "that when spray processing is used, the core particles must be at least about 75 to 100 μm or larger to obtain continuous coatings."

These arguments have been thoroughly considered, but were not found persuasive. Applicant has not established that less than 50 μm constitutes a critical maximum upper

limitation as to provide unexpected results over the prior art. Note that the specification permits the use of >50 μm which would include the range taught by Green ('577).

Secondly, Applicant argued, "Green does not cure the deficiencies of Moro, Sakon and Hanes. Green provides evidence that core particles obtained using known techniques must be at least 75 μm, more usually in the region of about 100-300 μm to achieve a uniform intact coating on the particle to achieve efficient freeze-dried dosage forms with slow drug release rate."

This argument has been considered but was not persuasive. Although Green *et al.* at column 3, lines 15-18, makes reference to, 'for example 75 to 400 μm', Green *et al.* also teaches that the particles generally have an average size of *up to about 500 μm.* The 'up to about 500 μm' would include particles having a particle size of <50 μm, as instantly claimed. Additionally, Green *et al.* claims, in claim 10, particles having a size in the range of 50 μm to 400 μm. Thus, Green *et al.* recognize the advantages obtained through the utilization of small particulate micron sizes.

Thirdly, Applicant argued, "The size of Applicant's claimed nanoscale thick (1 to 500 nm) coated drug particles (<50 μm in diameter) provide unique biological responses."

This argument has been considered but was not persuasive. The prior art clearly recognizes limitations of delivery based on micron size. The argument of the ability of smaller particles to be more successful in drug delivery via inhalation does not represent an unexpected result. The result is well known in the art. Moreover, one of ordinary skill familiar with this art would be fully capable of determining suitable or effective micron sizes, through the use of routine or manipulative experimentation to obtain the best possible results, dependent on the desired purpose.

Lastly, Applicant's arguments concerning the non-statutory obviousness-type double patenting over Talton (US '745) together with Lowndes et al. (US '599) have been fully considered, but were not found to be persuasive. The argument relating to the degree of purity obtained using lower pressure or Torr has not been established as being a patentably distinct difference, since the art teaches and recognizes obtaining similar coating thicknesses (using higher pressure) as that instantly claimed.

Thus, for the reasons advanced above, the instant invention remains unpatentable over the cited art of record.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H. N. Sheikh HNS

Patent Examiner

Art Unit 1615

November 30, 2004

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